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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,494	12/22/1999	MARTHA K. NEWELL	10277/7007	6216

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/470,494	NEWELL ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003 and 01 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,11-13,21,47 and 62-64* is/are pending in the application.

4a) Of the above claim(s) *2-6,47 and 62-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-13 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of the species of Group A, in vivo, in the Response to Restriction Requirement, filed 11/28/03, is acknowledged.

Applicant's previous election of CD86 as the co-stimulatory agent in applicant's Response, filed 6/9/03 and applicant's election of the CD40 ligand as the CD40 binding agent in applicant's Response, filed 8/6/01 with respect to Group I (claims 1-40 and 47-66) has been acknowledged.

In a telephone interview with applicant's representative Helen Lockhart on March 1, 2004, it was determined that the elected invention reads on the use of a multimeric CD40L as it reads on " (i) a first agent that binds a first CD40 receptor and (ii) a second crosslinking agent that crosslinks the first agent to at least a second receptor selected from the group consisting of a second CD40 receptor and a T cell receptor" (see claim 11).

Upon a review of the election, particularly as it reads on a "method of inducing T cell receptor rearrangement comprising a T cell with a CD40-binding agent that binds CD40 in an amount sufficient to induce T cell receptor gene rearrangement in the T cell in vivo; claims 1, 11-13 and 21 read on the elected invention.

Claims 1-6, 11-13, 21, 41-42, 47, 62-64, 67-69, 85 are pending in the instant application

Claims 1, 11-13 and 21 as they read on the elected invention of method of inducing T cell receptor gene rearrangement with CD40L in vivo are under consideration in the instant application.

Claims 2-6, 41-42, 47, 62-64, 67-69 and 85 have been withdrawn from consideration as being drawn to the non-elected inventions and/or species.
Given the claimed limitations of enriching T cells or enriched T cells, claims 2-6 read on the non-elected species of "in vitro".

Claims 7-10, 14-20, 22-40, 43-46, 48-61, 65-66, 70-84 and 86-103 have been canceled previously.

2. The filing date of the instant claims is deemed to be the filing date of priority application USSN60/114,106, filed 12/29/98.

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, see page 11, paragraph 1 of the instant specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate corrections are required

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. This is a rejection of 35 USC 112, first paragraph, scope of enablement as it reads on the elected "CD40L" and not on the breadth of "CD40-binding agent".

Claims 1, 11-13 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for CD40L multimers, including a CD40L trimer (e.g. see page 10, paragraph 2 of the instant specification), does not reasonably provide enablement for any CD40L, including "(i) a first agent that binds a first CD40 receptor and (ii) a second crosslinking agent that crosslinks the first agent to at least a second receptor selected from the group consisting of a second CD40 receptor and a T cell receptor" (see claim 11), as it reads on the elected invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

For example, oligomeric or multimeric CD40L act as agonists while monomeric CD40L acts as an antagonist (e.g. see U.S. Patent No. 6,290,972, particularly column 10, line 58 – column 11, line 8).

This distinction between agonistic or antagonistic forms of CD40L appears to be consistent with the instant disclosure, including as it reads on "(i) a first agent that binds a first CD40 receptor and (ii) a second crosslinking agent that crosslinks the first agent to at least a second receptor selected from the group consisting of a second CD40 receptor and a T cell receptor" (see claim 11), as it reads on the elected invention (see page 10, paragraph 2 of the instant specification).

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, making and using CD40L, while providing or maintaining the claimed activity to induce T cell receptor gene rearrangement by contacting a T cell with a CD40 binding agent that binds CD40 would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Applicant should amend the claims to recite the appropriate multimeric CD40L disclosed in the specification as filed that are enabled for the claimed methods to induce T cell receptor gene rearrangement in vivo.

6. Claims 11-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 11-12 are indefinite in the recitation of "CD40 receptor" because it appears that the specificity is "CD40" and not a receptor for CD40 (e.g. CD40 ligand or anti-CD40 antibodies).
Applicant is invited to amend the claims to recite CD40 for clarity.

B) Claims 11-12 are indefinite in the recitation of "(i) a first agent that binds a first CD40 receptor and (ii) a second crosslinking agent that crosslinks the first agent to at least a second receptor selected from the group consisting of a second CD40 receptor and a T cell receptor" (see claim 11), and "the method of claim 11, wherein the first agent that binds a first CD40 receptor is selected from the group consisting of a CD40 ligand and an anti-CD40 antibody (see claim 12) because the nature of structure of the "first and second agent" is ambiguous and unclear, including as it how it reads on the elected invention CD40L. For example, the specification discloses that the "the second receptor may be present on the surface of the same T cell as the first receptor, the second receptor may also be present on the surface of another T cell (see page 10, paragraph 1).

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:
A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 11-13 and 21 are rejected under 35 U.S.C. § 102(e) as being anticipated by Armitage et al. (U.S. Patent No. 6,290,972 B1) (see entire document).

Armitage et al. teach the in vivo administration of CD40L, including oligomers such as dimers or trimers , wherein said agonistic CD40L are useful as vaccine adjuvants (e.g. see columns 8-9, overlapping paragraph; column 10, paragraphs 2-3 and Claims).

Although the reference is silent about the induction of T cell receptor gene rearrangement, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to administer oligomeric CD40L as a vaccine adjuvant in vivo.

9. Claims 1, 11-13 and 21 are rejected under 35 U.S.C. § 102(e) as being anticipated by Maraskovsky et al. (U.S. Patent No. 6,497,876 B1) (see entire document).

Maraskovsky et al. teach the in vivo administration of CD40L, including oligomers such as dimers or trimers (e.g. see columns 7-10), wherein said agonistic CD40L are useful to stimulate immune responses in viv0 (column 11, paragraphs 3-4).

Although the reference is silent about the induction of T cell receptor gene rearrangement, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in

the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to administer oligomeric CD40L to stimulate immune responses in vivo.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Primary Examiner
Technology Center 1600
March 3, 2004